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| 10/718,266 | 11/21/2003 | Andre Jestin | 042049-0107 | 9067 |
| 22428 | 7590 | 04/27/2005 | EXAMINER | |
| FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | SALIMI, ALI REZA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,266

Applicant(s)

JESTIN ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-9 and 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/514,245.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/28/05, 5/14/04, 11/21/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Election/Restriction

Applicant's election with traverse of Group III (claims 3, and 10) in Paper filed 2/28/2005 is acknowledged. The traversal is on the ground(s) that search and examination of other groups would not be unduly burdensome. This is not found persuasive because the separate classification of the subject matter is a prima facie showing of burden, which is not overcome by Applicant's assertion to the contrary.

The requirement is still deemed proper and is therefore made FINAL.

Hence, claims 1, 2, 4-9, 11-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected. Claims 12, 13 are considered only within the scope of elected sequence SEQ ID NO: 29.

Applicants are reminded to cancel the non-elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior

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nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please update the information by inserting the U.S Patent number.

Claim Rejections - 35 USC § 112

Claims 3, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of utilizing ORF2 of Porcine Circovirus type 2 or type B only, does not reasonably provide enablement for method detecting antibodies against any and all circovirus in general, or porcine circovirus in particular. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims read on a detecting any all circoviruses, however, the specification only asserts that ORF2 is capable of recognizing the antibodies produced during infection by PWD circovirus type B (see specification page 19). Applicants' disclosure does not set forth antigenic properties of all circoviruses and one of ordinary skilled in the art would be forced in undue experimentations to enable the broad scope of the claimed invention. Applicants are reminded that the field of viral detection is considered to be highly unpredictable. According to the specification and the state of the art the currently claimed virus attacks the immune system and disables the immune response, thus, no antibodies would be present and absent teaching which polypeptide would be efficacious for detection, the skilled artisan would be forced to conduct

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large quantity of experimentations to enable the full scope of the claimed invention. Therefore, absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequence identified as ORF2 of Porcine Circovirus type 2 or type B. There is no information in the specification that indicates Applicants were in **possession** of the claimed “circoviruses” in general or “porcine circoviruses” in particular that can be utilized I the claimed invention. In

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addition, there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed agents. Therefore, a written description of the all other claimed circoviruses beside the ORF2 of circovirus should be disclosed to overcome this rejection. Hence, if the products were not possessed then the method of practicing the products were not possessed either. In order to practice the invention Applicants must have been in possession of claimed invention. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent

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pertaining to that cDNA=s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Ψ . Accordingly, the specification does not provide a written description of the invention Ψ .

and at pg 1406:

a generic statement such as Avertebrate insulin cDNA \cong or Amammalian insulin cDNA \cong without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and Ψ conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Ψ . Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tischer et al (Arch. Virology, 1995, Vol. 140: 737-743).

Tischer et al taught development of enzyme linked immunosorbent assay (ELISA) for detecting the porcine circovirus in pigs (see the abstract). In addition, they detailed the method of how to use the virus in detecting the circovirus antibodies (see page 738-739).

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Claims 3, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Allan et al (Veterinary Immunology and Immunopathology, 1994, Vol. 43: 357-371).

Allen et al taught development of enzyme linked immunosorbent assay (ELISA) for detecting the porcine circovirus in pigs (see the abstract). In addition, they detailed the method of how to use the virus in detecting the circovirus antibodies (see page 370, 3rd paragraph).

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Dulac et al (Cancer J. Vet. Res. 1989, Vol. 53, pages 431-433).

Dulac et al set forth development of enzyme linked immunosorbent assay (ELISA) for detecting the porcine circovirus in pigs (see the abstract, and page 431, last paragraph, page 432).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

4/25/2005

ALI R. SALIMI
PRIMARY EXAMINEE